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Mr. David Kropp  
Acting Director, Regulatory and Consumer Affairs  
Pharmavite Corporation  
P.O. Box 9606  
Mission Hills, California 91346

Dear Mr. Kropp:

This is in response to your letter of August 27, 2001 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Pharmavite Corporation is making the following claims, among others, for the product **Remdex with Andropan**:

“Feel Well Faster”

“...clinically proven to promote upper respiratory health and wellness and make you feel well faster”

“Helps you get back on your feet quickly”

“Begin taking REMDEX as soon as you feel the need to support the health of your head and chest”

Take temporarily until you feel well again. If desired results are not achieved after 5 days of continued use, consult your doctor”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended to treat, prevent, or mitigate a diseases of the upper respiratory tract. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

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Please contact us if you require further assistance.

Sincerely,

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John B. Foret

Director

Division of Compliance and Enforcement  
Office of Nutritional Products, Labeling,  
and Dietary Supplements

Center for Food Safety  
and Applied Nutrition

**Copies:**

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200

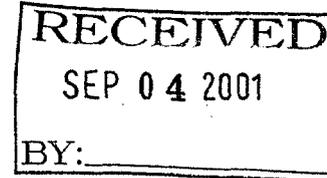
FDA, Los Angeles District Compliance, HFR-PA240



August 27, 2001

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Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C St. SW  
Washington, DC 20204



Dear Sir or Madam:

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act and Section 101.93 of FDA's regulations, we hereby notify you that we are using the following statement(s):

- (1) Name and address of manufacturer:  
Pharmavite Corporation, PO Box 9606, Mission Hills, CA 91346
- (2) Text of the statement(s):  
Clinically Proven  
Head & Chest Formula

Feel Well Faster  
Effective & Non-Drowsy  
All Natural

REMDEX™ is made with Andropan™, a unique extract of the plant *Andrographis paniculata* that has been clinically proven to promote upper respiratory health and wellness and make you feel well faster. Over 2000 years of use of this natural product in Chinese and Indian medical systems has demonstrated its effectiveness and safety.

Clinical studies show that all-natural REMDEX:  
Helps you get back on your feet quickly  
Strengthens your immune system function  
Provides a broad range of health benefits

Taken as directed, REMDEX is:  
Non drowsy  
Non-stimulative  
Safe & Effective



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Andropan™ is a clinically-proven extract of the plant *Andrographis paniculata*, standardized to 4% andrographolide.

**Suggested Use:** Begin taking REMDEX as soon as you feel the need to support the health of your head and chest. Take one tablet four times daily with water. Take temporarily until you feel well again. If desired results are not achieved after 5 days of continued use, consult your doctor.

**Caution:** Do not use if you have had allergic reactions to other products containing Andrographis or andrographolides. If allergic reactions develop during treatment, use of this product should be discontinued. Individuals using prescription medications should consult their doctor before taking this product. Do not use if you are pregnant or lactating. Not for use by individuals attempting to conceive children.

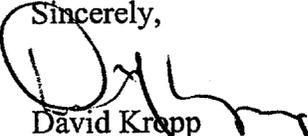
Color variation is normal in this product.

- (3) Name of the dietary ingredient if not provided in the text of the statement:  
Andrographis Extract (*Andrographis paniculata*) (aerial parts)
- (4) Name of the dietary supplement:  
Remdex with Andropan 300 mg

The above statement(s) may be used in one or more of the following brands of products: B.J.'s Wholesale, CVS, Duane Reade, Kirkland Signature, Jogmate, Nature Made, Nature's Resource, Optimize, Spring Valley, Walgreens.

We certify the information in this notice is complete and accurate, and we have substantiation that the above statement(s) is truthful and not misleading.

Sincerely,

  
David Kropp  
Acting Director, Regulatory and Consumer Affairs

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